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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/774,346	01/31/2001	Suggy S. Chrai	176650-96	2597

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EXAMINER

GEORGE, KONATA M

ART UNIT PAPER NUMBER

1616

DATE MAILED: 07/02/2003

16

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/774,346

Applicant(s)

CHRAI ET AL.

Examiner

Konata M. George

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 June 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 38-41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 38-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other:

DETAILED ACTION

Claims 38-41 are pending in this application.

Action Summary

1. Examiner acknowledges the cancellation of claims 1-10, 17-19 and 21-35, therefore the rejection of record under 35 U.S.C. 103(a) over Mlodozeniec is hereby withdrawn.

Allowable Subject Matter

2. The indicated allowability of claims 38-41 is withdrawn.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 38-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mlodozeniec (US Pat. No. 4,332,789).

Mlodozeniec discloses a product comprising a package which is a container and a plurality of solid, discrete pharmaceutical or diagnostic unit forms that are physically separated and independent of each other and in the form of a diagnostic reagent, a

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tablet, a caplet, a powder, or a capsule wherein each unit dosage form includes at least one active ingredient in an amount which does not vary from a predetermined target amount by more than 5 weight percent. The unit forms are attached to a planar base thermoplastic substrate film, covered by a second planar thermoplastic film and surrounded by a bond that joins the substrate film and the cover film. The ingestible thermoplastics are polyvinylacetate, hydroxypropyl methylcellulose, polyethylene oxide, polypropylene, polyester or polyamide. Mlodozeniec also discloses that the package may include multiple layers of unit forms. Mlodozeniec further discloses that optical scanning may be used in determining the amount of active ingredient (see abstract, fig. 6a-6d, col. 4, lines 21-31, col. 6, lines 13-21, col. 7, lines 32-44, col. 12, line 21 through col. 13, lines 25, 36-66, col. 16, lines 25-32, 57-68, col. 24, line 27 through col. 26, line 26 and col. 33, line 50 through col. 35, line 15). Mlodozeniec does not specifically disclose a substrate and a plurality of discrete pharmaceutical or diagnostic unit dosage forms or the unit dosage contains more than one active ingredient.

Mlodozeniec does generally disclose packaging in blister packs (col. 4, lines 25-31). The advantage of the blister packs is cost savings in handling and equipment. Therefore, it would have been obvious to one of ordinary skill in the art to use the teaching of Mlodozeniec to make a product comprising a substrate and a plurality of discrete pharmaceutical or diagnostic unit dosage forms associated with the substrate in the absence of factual showing to the contrary or a showing of unexpected results. Additionally, with regard to the recitation of a plurality of semi-spherical bubbles or a deposit having a substantially spherical shape, Mlodozeniec discloses that the cover

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forms a "basket shape" over the unit forms (see Figs. 6). A change in size or in shape in the absence of a change in function does not impart patentability (see *In re Rose*, 220 F.2 459, 105 USPQ 237 (CCPA 1955) and/or *In re Dailey*, 357 F.2 669, 149 USPQ 47 (CCPA 1966)). Column 34, lines 1-56, teaches the active agents that could be used, moreover, lines 54-56 teach that combinations of agents can be used, therefore it is the position of the examiner that this statement provides one of ordinary skill in the art the ability to use more than one active agent in the composition.

Response to Arguments

4. Applicant's arguments filed January 22, 2003 have been fully considered but they are not persuasive.

Applicants argue that Mladozeniec fails to suggest using a second active agent different from the first. Column 34, lines 54-56 teach that combinations of therapeutic agents can be used.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Telephone Inquiries

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konata M. George, whose telephone number is (703) 308-4646. The examiner can normally be reached from 8AM to 5:30PM Monday to Thursday, and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached at (703) 308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Konata M. George


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